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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/186,475	11/04/98	FONG	A 238/046

HM22/0524

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EXAMINER	
UNGAR, S	
ART UNIT	**PAPER NUMBER**
1642	10

DATE MAILED: 05/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/186,475	Fong et al
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Telephone Interview of April 7, 2001, Paper No. 10*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-3, 5-11, 15-24, and 27-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-3, 5-11, 15-24, and 27-32* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☒ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. Claims 1-3, 5-11, 15-24, 27-32 are pending in the application and are currently under prosecution. Upon review and reconsideration the previous restriction requirement is withdrawn.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

2. Upon review and reconsideration, this application contains claims directed to the following patentably distinct species of the claimed invention:

(A) Claims 1 and 2 are generic to a plurality of disclosed patentably distinct species comprising diseases manifested by different etiologies wherein the etiologies manifested are (a) cell proliferation, (b) cell differentiation, (c) cell survival, all of claim 2. Upon election of one of Species (a)-(c) Applicant is required to specifically disclose which of the conditions with different etiologies claimed in claim 3 read upon the elected species. Further, if more than one of the claimed diseases in claim 3 read upon the elected Species, Applicant is required to elect a single specific disease species for examination.

(B) Claim 1 and 5 are generic to a plurality of disclosed patentably distinct species comprising angiogenesis receptors with different structures and functions wherein the receptors are (a) Flt-1, (b) Flk-1, both of claim 6.

(C) Claims 1, 5 and 7 are generic to a plurality of disclosed patentably distinct species comprising antagonists with different structures and therefore different structures. Applicant is required to elected a single species from the group of eleven species claimed in claim 8 for examination.

(D) Claims 1 and 10 are drawn to a plurality of disclosed patentably distinct species comprising samples from different body tissues and fluids that have different structures and functions wherein the samples are (a) whole blood, or fraction thereof, monocytes (claims 10-11) (b) whole urine or fraction thereof (claim 10), (c) saliva or cell isolated therefrom (claim 10), (d) spinal fluid (claim 10), (e) amniotic fluid (claim 10), (f) endothelial cell biopsy (claim 10).

(E) Claims 1 and 15 are drawn to a plurality of disclosed patentably distinct species comprising markers related to angiogenesis with different structures and functions wherein said markers are (a) cell division (claim 15), (b) cell motility (claim 15), (c) cell proliferation (claim 15), (d) cell death (claim 15), (e) cell survival (claim 15), (f) cell differentiation (claim 15), (g) protein phosphorylation (claim 15), (h) protein expression (claims 15 and 16), (I) protein glycosylation (claim 15), (j) mRNA expression (claims 15, 16 and 20-21), (k) cell membrane potential (claim 15), (l) DNA division (claims 15 and 16), (m) DNA methylation (claim 15), (n) post translational modification of a protein (claim 15), (o) tissue factor (claims 22 and 32), (p) CD40 (claim 22), (q) u-PA (claim 22), (r) ETS-1 (claim 22), (s) IL8 (claim

22), (t) t-PA (claim 22), (u) VEGF mRNA (claim 27). Applicant is required to specifically disclose which of the markers claimed in claims 15, 16, 20-22, 27 and 32 read upon the elected species in Section 2(A) above, that is, the specific disease elected. Further, if more than one of the claimed markers in claims 15, 16, 20-22, 27 and 32 read upon the elected Species from Section 2(A) above, Applicant is required to elect a single specific marker species for examination.

(F) Claims 1 and 17 are drawn to a plurality of disclosed patentably distinct species comprising assays which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the assay is (a) an antibody assay (claim 18), (b) a blood clotting assay (claim 19).

(G) Claims 1 and 28 are drawn to a plurality of disclosed patentably distinct species comprising monitoring assays which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the assay is comprises (a) spectrophotometrical determination after addition of a specific chromogenic substrate, (b) detection with antibodies, (c) two stage clotting assay, (d) one-stage recalcification assay, (e) ELISA, (f) solid-phrase enzyme immunoassay employing polyclonal antisera, (g) hydrogen peroxide assay, (h) measurement of tissue factor mRNA levels in endothelial cells, all of claim 28. Applicant is required to specifically disclose which of the assay claimed in claim 28 read upon the elected species in Section 2(F) above, that is, the specific assay elected. Further, if more than one of the claimed assays in claims 28 read upon the elected Species from Section 2(F) above,

Applicant is required to elect a single specific marker species for examination. Further, if any of the claimed monitoring assays do not read upon the Species elected from Section 2(F) above, Applicant is required to identify said species. These species will be considered to be added to the species of Section 2(F) above and Applicant will be required to elect a single species for examination.

3. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
May 22, 2001

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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